K002542

OCT 23 2000

Section II: 510(k) Summary

GeniCon, L.C.
Contact: Gary Haberland
573 Waterscape Way
Orlando, FL 32828
Telephone: 407 273 7619
Fax: 407 306 9356

Date Prepared: August 11, 2000

Trade Name: GeniCon Reusable Cannula
Common Name: GeniCon Reusable Cannula
Classification Name: According to Section 513 of the Federal Food, Drug, Cosmetic Act, the device classification is Class II, performance Standards (21 CFR 878.4800).

Predicate Device: Dexterity Medical's Selecta-SEAL
1495 Hembree Road, Suite # 700
Roswell, GA 30076

Product Description:

The GeniCon Reusable Cannula is available in 70 & 100 mm length.

Indications for Use:

The GeniCon Reusable Cannula is intended for percutaneous insertion into the peritoneal cavity for the purpose of establishing a port of entry for instrumentation during laproscopic procedures.

Performance:

A series of performance tests were performed on the GeniCon Reusable Cannula to test such areas as:

1. Stress/Exposure Testing
2. Cleaning/Disinfection/Sterilization Testing

The FDA has not adopted performance standards for this product.

Conclusion:

Based on the indications for use, technological characteristics and performance testing, the GeniCon Reusable Cannula has been shown to be effective for its intended use and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Mr. Gary Haberland
Product Manager
GeniCon, LC
573 Waterscape Way
Orlando, Florida 32828

Re: K002542
Trade Name: GeniCon Reusable Cannula
Regulatory Class: II
Product Code: GCJ
Dated: August 11, 2000
Received: August 16, 2000

Dear Mr. Haberland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I: Indication for Use

510(k) Number: unassigned K002542

Device Name: GeniCon Reusable Cannula

Indications for Use:

The GeniCon Reusable Cannula is intended for percutaneous insertion into the peritoneal cavity for the purpose of establishing a port of entry for instrumentation during laproscopic procedures.

for Mark N Milliman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002542

GeniCon™
"New Ideas for Modern Health Care"